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Nove Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540

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APR 22 2005

OFFICE OF PETITIONS

In re Application of
Kjell Malmlof, et al.
Application No. 10/772,997
Filed: February 5, 2004
Attorney Docket No. 5904.214-US

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:
: **DECISION GRANTING**
:
: **PETITION**
:

This is a decision on the petition filed May 21, 2004, requesting that the above-identified application be accorded a filing date of February 5, 2004.

The petition is **GRANTED**.

The application was deposited on February 5, 2004. However, the Office of Initial Patent Examination mailed a "Notice of Incomplete Nonprovisional Application" (Notice) on May 6, 2004 stating that the application had not been accorded a filing date because the application was deposited without drawings.

In reply to the Notice, applicant filed the instant petition stating the drawings referenced in the application are incorporated by reference, but they also are not necessary for the understanding of the subject matter sought to be patented.

Since the petition states that drawings are incorporated by reference and are not necessary for an understanding of the invention, the application will be accorded the requested filing date without the drawing described in the specification.

This application file is being referred to the Office of Initial Patent Examination Division for further **processing with a filing date of February 5, 2004 without a drawing.**

Telephone inquiries concerning this matter may be directed to Marianne Jenkins at (703) 306-3475.

Brian Hearn
Senior Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy



Attorney Docket No.: 5904.214-US
USSN: 10/772,997
Filed: February 5, 2004

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Attorney Docket No.: 5904.214-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Malmlof et al.

Application No.: 10/772,997

Group Art Unit: Not Assigned

Filed: February 5, 2004

Examiner: Not Assigned

For: USE OF A GROWTH HORMONE OR A GROWTH
HORMONE SECRETAGOUGE FOR APPETITE-SUPPRESSION
OR INDUCTION OF SATIETY

PETITION TO ACCORD A FILING DATE UNDER 37 C.F.R. § 1.53(e)

Commissioner for Patents
Mail Stop Petitions
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice Of Incomplete Nonprovisional Application dated May 6, 2004, (copy attached), Applicants hereby petition the Office to accord the filing date of February 5, 2004 to this patent application pursuant to 37 C.F.R. § 1.53(e) and 37 C.F.R. § 1.181.

The US Patent and Trademark Office (hereinafter "the Office") issued a Notice of Incomplete Nonprovisional Application on May 6, 2004 (hereinafter "the Notice"). The Notice indicates that this patent application has not yet been accorded a filing date due to the failure to deposit the application with drawings.

Although this patent application refers to figures which were not included with the copy of the application filed on February 5, 2004, this application should still be accorded that filing date for at least two reasons.

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First, this application incorporates by reference U.S. Patent Application No. 10/140,512, which contains identical copies of the referenced figures and description thereof. Applicants note that the subject application is a continuation of the '512 application. This application is identical to the '512 application in the specification (modifications in the claims of this application are fully supported by the text of the '512 application). Under Office policy, information incorporated by reference is considered "as much a part of the application as filed as if the text was *repeated in the application*, and should be treated as part of the text of the application *as filed*." See, e.g., MANUAL OF PATENT EXAMINING PROCEDURE (hereinafter "MPEP") § 2163.07(b) (emphasis added). Accordingly, Applicants request that this application be accorded the filing date of February 5, 2004, and that the figures of the '512 application be considered in the examination of this application. If necessary, Applicants' representative can submit a formal affidavit regarding the incorporation of this material.

Second, in the event the Office deems the incorporation of this material ineffective for according this application the February 5, 2004 filing date, Applicants, *alternatively* request that this application be accorded that filing date due to the fact that the referenced figures, while beneficial in illustrating Applicants' invention, are not necessary to understanding the claims of this application and, accordingly, are not required under 35 U.S.C. § 113 (hereinafter "Section 113") (see also MPEP § 601.01(f) for discussion of related principles). Specifically, the claims of this application are directed to methods of suppressing appetite (1-7 and 14-16), preventing diseases or disorders (8-13), and a composition formulated for injection (17). None of the claims are directed to any subject matter that relies upon the content of the "missing" figures for support. Applicants note that "It has been USPTO practice to treat an application that contains at least one process or method claim as an application for which a drawing is not necessary for an understanding of the invention under 35 U.S.C. 113 (first sentence)." See MPEP § 601.01(f). "The same practice has been followed in composition applications." *Id.* The claims of this application fall within these categories and do not require the drawings for support. Accordingly, even if the Office should not accord this application the February 5, 2004 filing date based upon the

Attorney Docket No.: 5904.214-US
USSN: 10/772,997
Filed: February 5, 2004

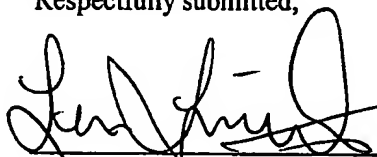
incorporation of the parent '512 application, it should do so based on the nonnecessity of the figures under Section 113. Applicants strongly believe that the Office should accord this application the February 5, 2004 filing date due to the incorporation and *only* wish to rely on this alternative request *if absolutely necessary* to accord the application the February 5, 2004 filing date.

For the foregoing reasons, Applicants respectfully request that this application be accorded the filing date of February 5, 2004, and that examination of this application thereafter proceed on the merits. To the extent permissible, Applicants also request permission to submit copies of the figures incorporated by the reference to the parent '512 application in this application and that the Examiner considers such figures in the examination of this application.

Please charge the required fee (under 37 C.F.R. § 1.17(h)), estimated to be \$130.00, to Novo Nordisk Pharmaceuticals, Inc., Deposit Account No. 14-1447. A duplicate of this sheet is enclosed. Upon grant of this Petition, Applicants respectfully request a refund of this fee, which may be made by deposit to this Deposit Account.

Respectfully submitted,

Date: May 18, 2004

A handwritten signature in black ink, appearing to read 'Len S. Smith', written over a horizontal line.

Len S. Smith, Reg. No. 43,139
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
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Use the following customer number for all correspondence regarding this application

23650

PATENT TRADEMARK OFFICE

**TITLE: USE OF A GROWTH HORMONE OR A GROWTH HORMONE SECRETAGOGUE
FOR APPETITE-SUPPRESSION OR INDUCTION OF SATIETY**

5 CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Serial No. 10/140,512 which is a continuation of PCT/DK00/00600 filed on October 27, 2000, and claims priority under 35 U.S.C. 119 of Danish application no. PA 1999 01585 filed on November 3, 1999, and U.S. provisional application no. 60/165,491 filed on November 15, 1999, the contents of which are
10 fully incorporated herein by reference.

FIELD OF INVENTION

The present invention relates to use of growth hormone for the manufacture of a medicament for appetite-suppression or induction of satiety. The invention also relates to a
15 method for suppressing appetite or inducing satiety.

BACKGROUND OF THE INVENTION

Growth hormone is a hormone, which stimulates growth of all tissues capable of growing. The growth hormones (GH) from man and from the common domestic animals are
20 proteins of approximately 191 amino acids, synthesized and secreted from the anterior lobe of the pituitary gland. Human growth hormone consists of 191 amino acids.

Growth hormone is released from the pituitary. Growth hormone is a key hormone involved in the regulation of not only somatic growth, but also in the regulation of metabolism of proteins, carbohydrates and lipids. The organ systems affected by growth hormone include the
25 skeleton, connective tissue, muscles, and viscera such as liver, intestine, and kidneys. The major effect of growth hormone is to promote growth. Deficiency in growth hormone can result in a number of severe medical disorders, e.g., dwarfism. Furthermore, growth hormone has been proposed for increasing the rate of growth of domestic animals or for decreasing the proportion of fat in animals to be slaughtered for human consumption.

30 Growth hormone is known to have a number of effects on metabolic processes, e.g., stimulation of protein synthesis and free fatty acid mobilisation and to cause a switch in energy metabolism from carbohydrate to fatty acid metabolism. The main features of the lipolytic effect of growth hormone are rapid increase in circulating levels of free fatty acids (FFA), oxygen consumption and energy expenditure followed by decreases in fat deposits.

35 Suppression of food intake is important. Obesity is a well-known risk factor for the development of many very common diseases such as atherosclerosis, hypertension, Type II